



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/803,126

03/17/2004

James Robert Schwartz

9183M&

4865

27752

7590

08/10/2006

THE PROCTER & GAMBLE COMPANY
INTELLECTUAL PROPERTY DIVISION
WINTON HILL BUSINESS CENTER - BOX 161
6110 CENTER HILL AVENUE
CINCINNATI, OH 45224

EXAMINER

ARNOLD, ERNST V

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 08/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,126

Applicant(s)

SCHWARTZ ET AL.

Examiner

Ernst V. Arnold

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11, 12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-9, 11, 12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: ____.

DETAILED ACTION

The Examiner has carefully considered Applicant's remarks filed on 6/1/2006.

This action is final. Claims 10 and 13 have been cancelled. Accordingly, claims 1-9, 11, 12 and 14-25 are pending.

Withdrawn rejections/objections:

1. Claims 2, 3 and 19 were objected to because of minor informalities. Applicant has corrected the informalities and the objections are withdrawn.
2. Claims 1-14 and 23-25 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended claim 1 to overcome this rejection and it is withdrawn.
3. Claims 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicant has amended claims 11, 12 and 14 to overcome this rejection and it is withdrawn.
4. Claims 1, 8, 9, 13, 14 and 23-25 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 11, 12, 38-42 and 51-53 of copending Application No. 10/742,557. Applicant asserted that the crystallite size is not merely a matter of routine optimization and directed the Examiner to pages 33-36 of the specification to demonstrate that the results were not merely routine optimization. The Examiner finds this persuasive and withdraws the double patenting rejection.

Art Unit: 1616

5. Claims 1, 5-8, 13 and 23-25 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 9, 18-21 and 26-28 of copending Application No. 11/100,648. Applicant asserted that it is not obvious to add a cationic polymer with a trimethylamine level of less than about 45 ppm and the pH is greater than about 6.8 and an effective amount of a surfactant with an anionic functional group. The Examiner finds this persuasive and withdraws the double patenting rejection.

6. Claims 1, 5-9, 13, and 23-25 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 7, 18-21 and 30-32 of copending Application No. 11/216,520. Applicant asserted that the limitation of less than 5.5 micromoles of a zinc binding material per gram of the particulate zinc material/per m²/gram surface area of the particulate zinc material is not obvious. Upon further consideration, the Examiner finds this persuasive and withdraws the rejection.

8. Claims 1, 8, 9 and 13 were rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3 and 5 of U.S. Patent No. 6,908,912. Applicant asserted that the '912 patent discloses an organic amine component in an amount of from about 30% to about 80% and that the Declaration by Dr. Schwarz states the difference between zinc carbonate and basic zinc carbonate. While not finding the declaration persuasive, the Examiner finds the organic amine limitations persuasive and distinguishing and withdraws the rejections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-9, 11, 12, 14-17 and 23-25 remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Gavin et al. (WO 01/00151).

Gavin et al. disclose a topical anti-dandruff composition for treating microbes comprising from 0.001 to 10% zinc pyrithione; from 0.001 to about 10% of a zinc salt, such as zinc carbonate, and an anionic deterative surfactant for a topical carrier thus reading on instant claims 1-3, and 15-17 (Claims 1 and 6). The zinc salt can be the insoluble particulate zinc carbonate anticipating instant claims 5-8 (Claim 6). Please note that the Examiner interprets zinc carbonate to be synonymous with basic zinc carbonate as defined in the instant specification (Page 4, lines 11-34; and page 5, lines 16-18). The zinc-containing layered material (zinc carbonate) is present from 0.001% to 10% by weight of the composition preferably 0.1% to 2% by weight and in a ratio of to the antimicrobial active agent (zinc pyrithione) from about 5:100 to about 5:1 (claim 1). Please note that since the composition is the same and in the same proportions as the instantly claimed invention, then the composition of Gavin et al. would inherently have an augmentation factor of greater than 1. The Patent and Trademark Office is not equipped with the scientific equipment to compare the composition of Gavin et al. to the instantly claimed invention but when the compositions are comprised of the exact same

materials and would inherently have the exact same properties then the burden is appropriately shifted to the Applicant to demonstrate unexpected results otherwise.

Gavin et al. disclose zinc pyrithione as a preferred metal salt of pyrithione thus reading on instant claim 9 (claim 1). Gavin et al. disclose a range of 0.001 to 10%; 0.1 to 2% and 0.01 to 5% by weight of the composition of the metal ion source (i.e., zinc carbonate) which reads on instant claim 10 and anticipates the ranges of 0.01 to about 7% in instant claim 11 and 0.1% to 5% of instant claim 12 (claims 1, 5 and 6). Gavin et al. disclose the zinc pyrithione as being 0.001% to 10% and preferably 0.1% to 2% by weight of the composition in claim 1 and disclose a range of 0.1 to 5% by weight of the composition in claim 2 and thus anticipating the ranges of instant claims 13 and 14.

Methods pertaining to treating microbial infections preferably related to dandruff and treating athlete's foot, a contagious fungal infection, are provided hence anticipating instant claims 23-25 (Claim 9).

Response to arguments:

Applicant asserted that they do not concede that the instantly claimed materials are the same as those of Gavin et al. Applicant submitted a Declaration of James R. Schwarz under 37 CFR 1.132 to distinguish between zinc carbonate and basic zinc carbonate. The Examiner has carefully considered this declaration by Dr. Schwarz. However, the Examiner is maintaining his position that zinc carbonate and basic zinc carbonate are synonymous as evidenced by the material safety data sheet from Mallinckrodt Baker, Inc; a global supplier of high purity fine chemicals. The MSDS for zinc carbonate states that basic zinc carbonate is a synonym and has a chemical

formula of $3\text{Zn}(\text{OH})_2\cdot 2\text{ZnCO}_3$ (MSDS zinc carbonate, page 1 of 7). And because the terms are synonymous, the composition of Gavin et al. reads upon the instant invention and the Examiner maintains the rejection.

Claim Rejections - 35 USC § 102

Claim 22 remains rejected under 35 U.S.C. 102(b) as being anticipated by Biener (US 4,943,432).

Claim 22 is drawn to a process for preparing a basic zinc carbonate-containing personal care composition comprising reacting a carbonate or bicarbonate salt with a zinc compound to form in-situ the basic zinc carbonate.

Biener discloses a composition for the treatment of psoriasis and other skin diseases comprising zinc chloride (a zinc salt of an inorganic acid) and sodium carbonate (Abstract; Column 4, lines 47-48 and claim 8, for example). Biener discloses the treatment of hundreds of patients by bathing in solutions of the salt mixtures or application of the mixtures to the skin (Column 3, lines 13-23). Thus, solutions comprising the zinc salt and the sodium salt would have inherently reacted in the mixture and produced basic zinc carbonate in-situ thus reading on the process of instant claim 22.

Response to arguments:

Applicant concedes that Biener does disclose a composition that contains carbonate and zinc and Applicant asserts that other components present may react with the zinc and carbonate to prevent or impede formation of zinc hydroxycarbonate. The

Art Unit: 1616

Examiner notes that the comprising language of claim 22 allows for additional components and if only one molecule of zinc carbonate forms in the composition of Biener then it would read upon the instant invention and be anticipated. The Examiner does not have access to a chemical laboratory to test the composition of Biener but it is reasonable to suggest that the composition of Biener would inherently form some zinc hydroxycarbonate in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 102

Claim 22 is rejected under 35 U.S.C. 102(b) as being anticipated by Cilley et al. (US 4,933,101).

Cilley et al. disclose a detergent composition comprising sodium carbonate and zinc oxide (Column 22, lines 1-23). Cilley et al. provide methods of making the composition, which comprises paddling the zinc oxide into a pre-mixed sodium carbonate containing mixture (Column 22, lines 25-44). Since the components are the same in the Cilley et al. disclosure as the instantly claimed composition then it would have formed basic zinc carbonate in-situ and anticipate the instant invention.

Please note: With respect to the art rejection above, it is noted that the reference does not teach that the composition can be used in the manner instantly claimed, a personal care composition, however, the intended use of the claimed composition does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must create a structural difference between the claimed composition and the prior art

Art Unit: 1616

composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting. Please note that when applicant claims a composition in terms of function and the composition of the prior art appears to be the same, the Examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection (MPEP 2112).

Response to arguments:

Applicant asserted that the reference of Cilley et al. is non-analogous art. The Examiner maintains that the reference of Cilley et al. is directed to cleaning compositions using the same carbonate and zinc components as instantly claimed and thus reads on the instant invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gorman (US 4,161,526) in view of Daley (US 3,960,782).

Gorman discloses a skin cleansing composition comprising zinc pyrithione, water, an alcohol and zinc oxide (Column 2, lines 23-51). Gorman discloses a method to make the composition where the additional zinc component was added to the zinc pyrithione/water/alcohol composition and the result produced a much better looking

product (Column 2, lines 41-51). Zinc hydroxide may be used in the composition (Column 2, lines 7-9 and claims 1 and 4).

Gorman does not expressly disclose the addition of a bicarbonate/carbonate salt to the composition that would react in-situ with the zinc salt to produce basic zinc carbonate within a range of between about 1:10 and about 10:1.

Daley et al. provide a general teaching of conventional ingredients in the formulation of shampoos (Column 3, lines 17-19). Daley et al. disclose that sodium carbonate is a suitable pH-adjusting agent and zinc pyridinethiol-N-oxide is a suitable anti-dandruff agent (Column 3, lines 23-27).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Gorman by adding sodium carbonate as suggested by Daley et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Daley et al. disclose that sodium carbonate is a conventional pH adjusting reagent in shampoo compositions. The adjustment of particular working conditions, (i.e., the ratio of carbonate salt to zinc salt), is deemed merely a matter of routine optimization of conventional working conditions, which is well within the purview of one of ordinary skill in the art.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because

every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the combined teachings of the cited references.

Response to arguments:

Applicant asserted that neither Gorman nor Daley disclose or suggest a zinc hydroxycarbonate containing personal care composition much less a process for reacting a carbonate or bicarbonate salt with a zinc compound to form zinc hydroxycarbonate in situ and that there is no motivation to combine the two references. The Examiner respectfully disagrees with this opinion. While it is true that neither Gorman nor Daley disclose or suggest a zinc hydroxycarbonate containing personal care composition, Daley teaches, as stated in the prior office action, that the addition of sodium bicarbonate is conventional in the art of shampoo formulation meaning that one of ordinary skill in the art would know of this reagent. One of ordinary skill in the art would have wanted the best hair luster and manageability as taught by Daley et al. and applied the concepts taught there to the zinc pyrithione shampoos suggested by Gorman.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

Art Unit: 1616

F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5-9 and 23-25 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5, 14-17 and 23-24 of copending Application No. 10/802,166. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention embrace or are embraced by the claims in the co-pending application as is shown in the claims analysis table below.

Instant Application 10/803,126	Common claim elements	Copending Application 10/802,166 (03/17/2004)
1	Zinc-containing layered material; metal salt of pyrrhione	1 and 2
1 and 5	Zinc-containing material is basic zinc carbonate	1, 2 and 14
1 and 6	Zinc-containing material is basic zinc carbonate	1, 2 and 15
1 and 7	Zinc-containing material is basic zinc carbonate	1, 2 and 16
1 and 8	Zinc-containing material is basic zinc carbonate	1, 2 and 17
1 and 9	Zinc pyrrhione	1-3
1, 2 and 23	Method of treating microbial infections	1 and 23
1, 2 and 24	Method of treating fungal	1 and 24

	infections	
1, 2 and 25	Method of treating dandruff	1 and 25

One of ordinary skill in the art would have recognized that the composition comprising a zinc-containing layered material; a surfactant; and a metal salt of pyrithione is encompassed by the composition of the co-pending application comprising a metal salt of pyrithione and a zinc-containing layered material. Since the compositions are the same then the compositions are would inherently have the same characteristics including lability of the zinc. The addition of anionic surfactants to zinc pyrithione dandruff shampoos has been suggested by Bowser et al. (US 5,723,112) (Abstract; column 3, lines 19-41 and claims 1-8, for example). The selection of surfactants (i.e., surfactants with anionic functional groups) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of one of ordinary skill in the art. The comprising language of the instant invention does not preclude the addition of surfactants with anionic functional groups. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to arguments:

Applicant asserted that Application 10/802,166 is directed towards a composition comprising a zinc containing layered material; a surfactant with an anionic functional group and wherein the zinc containing layered material has a relative zinc lability of greater than 15%. The Examiner notes that the comprising language of the instant invention does not preclude the addition of anionic surfactants, which, as noted in the

previous office action, are common to add to shampoos. In addition, since the components of the composition appear to be the same then they would have the same properties including zinc lability.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

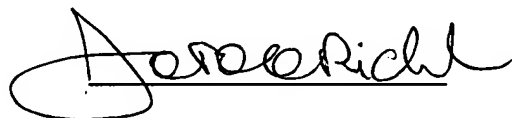
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F (6:15 am-3:45 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ernst Arnold
Patent Examiner
Technology Center 1600
Art Unit 1616

A handwritten signature in black ink, appearing to read "Johann Richter", with a large, stylized loop at the beginning.

Johann Richter, Ph.D. Esq.
Supervisory Patent Examiner
Technology Center 1600